Notice of FDA Warning regarding the use of vaginal mesh:

The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare.

The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

The FDA will provide updates on its Web page:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm.

Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update

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Introduction

Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations studied.[1] A large meta-analysis reported an estimated prevalence for urinary incontinence of 30% in women aged 30 to 60 years, with approximately half of the cases attributed to SUI;[2] another study reported the prevalence of SUI was 5% to 30% in European women.[3] Many women in the United States (U.S.) elect to have a surgical procedure for management of their SUI symptoms each year. The first Female Stress Urinary Incontinence Clinical Guidelines Panel reviewed literature available up to January 1994 and published its report in 1997.[4] Since that time, a new body of literature has emerged on primarily novel surgical interventions for the treatment of SUI. For these reasons, the American Urological Association (AUA) has elected to update the initial report on the Surgical Management of Stress Urinary Incontinence. The literature search used in this analysis had a conclusion date of June 2005; it is recognized that this guideline will likely change in response to new information and further developments in the field.

In the 1997 guideline, the index patient was an otherwise healthy female patient with SUI without significant pelvic organ prolapse. It has become apparent since the prior guideline that many women with SUI also have pelvic organ prolapse and that these two issues may be addressed concurrently. Therefore, in constructing this guideline update, the index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and prolapse who elects to have treatment of her

SUI along with surgical correction of prolapse. The current Female Stress Urinary Incontinence Guideline Update Panel (the Panel) was selected by the Panel chair and approved by the Practice Guidelines Committee (PGC) of the AUA. The Panel members are representative of different medical specialties and geographic regions of the U.S. and are from both academic and private institutions.

This report describes an analysis of efficacy and safety outcomes for surgical procedures for use in treatment of SUI and provides a guideline based on review of these data and/or panel consensus. It also offers a discussion about the diagnostic evaluation of the index patient and recommendations for outcomes reporting and future research.

Definitions

Stress urinary incontinence is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions. There are two principle causes of this symptom – SUI and the rarer stress-induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure). The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies. For the purposes of this guideline, it is assumed that patients in the extracted studies had surgical management of SUI.

Urgency refers to a sudden, compelling desire to pass urine which is difficult to defer[5] or a strong need to pass urine for fear of leakage.[6] Urge urinary incontinence is defined as

involuntary leakage accompanied by or immediately preceded by urgency.[5] Mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.

Index patient

The index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and pelvic organ prolapse who elects to have treatment of her SUI along with surgical correction of pelvic organ prolapse. Either index patient may be untreated or previously surgically-treated and may have urethral hypermobility and/or intrinsic sphincter deficiency. Urethral hypermobility was defined by the author; no uniform definition was used.

Methodology

This guideline included analysis of those relevant factors (perceived risks and outcomes of the interventions, patient preferences and relative priorities of the interventions given limited health care resources) used to choose among alternative treatment interventions.[7] The peer-reviewed medical literature was meta-analyzed to estimate outcomes of treatment modalities, and Panel members themselves served as proxies for patients in considering preferences. The steps taken to develop this guideline, further detailed in Chapter 2, included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval and dissemination. The Panel did not review needle suspensions or anterior colporrhaphy in

developing this guideline update. Since development of the 1997 guideline, very limited new data has been published addressing these procedures, and there is a lack of current use or interest in them as well. Though these operations may still be performed in isolated circumstances by some surgeons, the Panel believes that they are largely of historical interest only and no longer considers these procedures contemporary treatments for SUI.

Problem Definition

This guideline update was based on the original AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997 using a similar methodology. The analysis was likewise limited to surgical treatments but included new procedures and those considered the most efficacious as determined by the previous analysis. Unlike the 1997 guideline, outcomes of surgical therapies for prolapse were also included.

Surgical efficacy was defined in three parts: 1) the resolution and lack of recurrence of SUI and urgency; 2) the resolution of prolapse and the lack of recurrence or new onset of prolapse; and 3) the incidence and severity of adverse events of these treatments. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on patient quality of life. The treatments included in the analysis were retropubic suspensions, slings, injection therapy and artificial sphincters; the analysis excluded those procedures not generally available in the U.S. or not expected to be approved at the time of publication. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. Procedures used to correct prolapse included hysterectomy in conjunction with or as a component of surgical treatment of SUI and site-specific repairs.

Literature Search and Data Extraction

A database was generated that included articles retrieved for the previous guideline and those resulting from a series of four MEDLINE® searches beginning in December 2002 and concluding in June 2005. The searches were limited to papers involving human subjects and published in the English language on or after 1990 which included the MeSH term "female." The MeSH headings used were "urinary incontinence, stress," "stress incontinence" and "urinary incontinence" in any field. A total of 7,111 citations and abstracts were reviewed for relevance by the panel chairs, of which 1,302 citations entered the extraction process. Panel members extracted data from the articles which were then entered into a Microsoft Access® (Microsoft, Redmond, WA) database. In person and via conference calls, the Panel collectively reviewed the extracted data. A total of 436 articles were suitable for inclusion in the meta-analysis; an additional 155 articles were deemed suitable only for their complications data due to an insufficient follow-up duration for the efficacy outcomes analysis.

Evidence Combination

To generate outcomes tables, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Combination can be performed in a variety of ways depending on the nature and quality of the evidence. For this guideline, the panel used the confidence profile method,[8, 9] which provides methods for meta-analyzing data from studies that are not randomized controlled trials (RCTs). Meta-analysis was performed using the Fast*Pro software to combine individual arms from controlled trials and clinical series where similar patients were similarly treated. Although a number of RCTs were found through the literature search, there were insufficient numbers on any one topic to warrant an independent meta-analysis of RCTs. The results of

certain trials are discussed where relevant. Frequently, published series used in a combined analysis showed very divergent results implying site-to-site variations, variability in patient populations, in the performance of the intervention, the skill of the surgeon or normal statistical variation. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

Patient Groups

While stratifying outcomes based on patient characteristics such as type of incontinence, previous treatment(s), presence of prolapse, prior pregnancy and severity of incontinence would be most instructive, in most cases the outcomes data were not fully or consistently identified by these criteria. Therefore, analysis was limited to two patient groups; one in which no patient received concomitant surgical treatment for prolapse (comparable to the previous guideline) and another in which some or all patients received concomitant treatment for prolapse. Very few published studies included all of the SUI patients receiving concomitant prolapse treatment, therefore, the analysis was based mainly on data from studies that included some patients with prolapse treatment. This did not permit a clear distinction to be made between these groups in the analysis. An attempt to stratify the outcomes of SUI surgical interventions by the presence of prolapse was thwarted by insufficient data since few published studies stratified results in this manner.

Efficacy Analysis

The efficacy outcomes analyzed included two levels of continence: cured/dry and cured/dry/improved; these are reported percentages and credible intervals (Bayesian confidence intervals [CIs]). Allocation to the previously mentioned categories was determined by author definition of continence. For the analysis of postoperative urgency, patients were divided into

three categories: without pre-existing urgency, with pre-existing urgency, and unknown or uncertain pre-existing urgency. Postoperative urgency categories included urge incontinence, urge symptoms and unspecified. Again, the results are reported as the percent of the relevant patient group having each outcome. Abbreviated tables summarizing the cured/dry and resolution or urge incontinence for the time interval of 12-23 months for patients with or without concurrent prolapse treatment are provided with this document (see Tables 1–3); for a complete set of data tables see Appendices A7-A16.

Complications

Complications were analyzed similarly to the efficacy outcomes. However, because of the wide variety of ways authors name and describe complications, the panel attempted to group complications together that represented the same or related outcomes. As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Appendix A-17 shows how the panel grouped outcomes. Certain complication outcomes such as pain and de novo urgency were tabulated as defined by the author, and no further analysis was performed based upon the limitations of data reporting. After grouping the complications for analysis, the grouped complications were then put into general categories for display and discussion. Outcomes tables were developed for each group of complications. Separate tables were again created for patients with and without prolapse treatment. The format of the tables is the same as the efficacy tables. An abbreviated table summarizing retention data for patients with or without concurrent prolapse treatment is provided with this document (see Table 4); for a complete set of data tables see Appendices A7 – A16.

Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel

Complications ANY Prolapse**

	Suspensions								
	All Retropubic Suspensions			Burch Suspension			Laparoscopic Suspension		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death									
Transfusion	7/415	6%	(2 - 14)%	6/375	7%	(2 - 16)%	5/183	2%	(1 - 6)%
General Medical Complications									
Cardiovascular	3/342	2%	(1 - 4)%	3/342	2%	(1 - 4)%	3/185	3%	(1 - 6)%
Febrile	7/614	11%	(5 - 20)%	5/513	14%	(6 - 26)%	3/296	2%	(1 - 5)%
Infection	2/280	12%	(6 - 19)%	2/280	12%	(6 - 19)%			
Infection/Local Extension	1/51	3%	(1 - 7)%	1/51	3%	(1 - 7)%	2/164	3%	(1 - 9)%
Neurologic									
Pulmonary	1/33	4%	(0 - 13)%				2/151	3%	(1 - 7)%
Systemic - Abscess	1/82	4%	(1 - 9)%	1/82	4%	(1 - 9)%	2/149	3%	(1 - 8)%
UTI	10/779	17%	(11 - 25)%	10/779	17%	(11 - 25)%	11/545	7%	(5 - 11)%
Operative Complications									
Bladder Injury	8/503	3%	(2 - 6)%	8/503	3%	(2 - 6)%	16/901	6%	(4 - 8)%
Bleeding									
Bleeding - Acute	2/177	5%	(1 - 13)%	2/177	5%	(1 - 13)%	2/98	2%	(0 - 8)%
Bleeding - Hematoma	9/600	5%	(3 - 7)%	8/560	5%	(3 - 7)%	7/366	3%	(2 - 6)%
Bowel Injury	2/150	2%	(0 - 6)%	1/82	1%	(0 - 6)%	3/182	3%	(1 - 8)%
Erosion Extrusion									
Erosion Extrusion - Unknown									
Erosion Extrusion - Urethral-Bladder	2/147	2%	(0 - 5)%	2/147	2%	(0 - 5)%	4/201	6%	(2 - 11)%
Erosion Extrusion - Vaginal									
Nerve Injury									
Operative CX - Other	1/127	1%	(0 - 4)%	1/127	1%	(0 - 4)%	1/36	1%	(0 - 7)%
Osteomyelitis	2/2	71%	(23 - 98)%		*				
Ureteral Injury		*			*		3/109	4%	(1 - 10)%
Urethral Injury									
Urinary Tract Injury NS		*			*				
Vaginal Operative CX							1/113	1%	(0 - 4)%
Wound	5/408	5%	(3 - 9)%	5/408	5%	(3 - 9)%	4/206	4%	(1 - 8)%
Abdominal	3/233	5%	(1 - 12)%	1/132	1%	(0 - 3)%	4/155	7%	(2 - 18)%
Vaginal							1/48	0%	(0 - 5)%
Subjective Complications									
Pain	2/76	9%	(2 - 24)%	2/76	9%	(2 - 24)%	7/353	3%	(2 - 6)%
Sexual Dysfunction	5/262	7%	(4 - 12)%	5/262	7%	(4 - 12)%	1/34	12%	(4 - 26)%
Voiding Dysfunction	3/314	16%	(5 - 33)%	3/314	16%	(5 - 33)%	3/104	8%	(3 - 15)%
Conversion							3/219	11%	(5 - 20)%
Other Complications	3/183	8%	(4 - 14)%	3/183	8%	(4 - 14)%	1/36	6%	(1 - 17)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel
Complications
ANY Prolapse**

	Slings								
	Autologous fascia			Autologous Vaginal Wall Slings					
	without Bone Anchors			with/without Bone anchors			w Bone Anchors - Suprapubic		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death									
Transfusion	1/198	4%	(2 - 7)%	2/35	9%	(2 - 24)%			
General Medical Complications									
Cardiovascular				1/15	8%	(1 - 27)%			
Febrile									
Infection	1/80	4%	(1 - 10)%	2/32	22%	(8 - 42)%			
Infection/Local Extension									
Neurologic									
Pulmonary	1/80	10%	(5 - 18)%						
Systemic - Abscess									
UTI	1/80	8%	(3 - 15)%	1/20	1%	(0 - 12)%			
Operative Complications									
Bladder Injury	2/278	8%	(1 - 26)%	1/82	3%	(1 - 8)%			
Bleeding									
Bleeding - Acute	1/80	8%	(3 - 15)%	1/20	6%	(1 - 21)%			
Bleeding - Hematoma									
Bowel Injury	1/80	1%	(0 - 6)%						
Erosion Extrusion									
Erosion Extrusion - Unknown									
Erosion Extrusion - Urethral-Bladder		*		1/20	1%	(0 - 12)%			
Erosion Extrusion - Vaginal									
Nerve Injury									
Operative CX - Other				1/82	1%	(0 - 6)%			
Osteomyelitis								*	
Ureteral Injury				1/20	1%	(0 - 12)%			
Urethral Injury									
Urinary Tract Injury NS									
Vaginal Operative CX									
Wound	2/278	4%	(2 - 8)%						
Abdominal				1/82	3%	(1 - 8)%		*	
Vaginal				2/65	3%	(0 - 11)%			
Subjective Complications									
Pain	1/80	3%	(1 - 8)%	1/45	3%	(0 - 10)%			
Sexual Dysfunction									
Voiding Dysfunction									
Conversion									
Other Complications									

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel
Complications
ANY Prolapse**

	Slings								
	Cadaveric						Homologous Tissue (Dermis)		
	with Bone Anchors			without Bone Anchors			without Bone Anchors		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death									
Transfusion									
General Medical Complications									
Cardiovascular									
Febrile				1/36	6%	(1 - 17)%			
Infection									
Infection/Local Extension									
Neurologic									
Pulmonary									
Systemic - Abscess									
UTI									
Operative Complications									
Bladder Injury				1/36	3%	(0 - 12)%			
Bleeding									
Bleeding - Acute									
Bleeding - Hematoma									
Bowel Injury									
Erosion Extrusion									
Erosion Extrusion - Unknown									
Erosion Extrusion - Urethral-Bladder									
Erosion Extrusion - Vaginal		*					1/19	6%	(1 - 22)%
Nerve Injury									
Operative CX - Other									
Osteomyelitis									
Ureteral Injury							1/19	1%	(0 - 12)%
Urethral Injury									
Urinary Tract Injury NS									
Vaginal Operative CX									
Wound									
Abdominal									
Vaginal									
Subjective Complications									
Pain									
Sexual Dysfunction									
Voiding Dysfunction									
Conversion									
Other Complications									

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel
Complications
ANY Prolapse**

	Slings: Synthetic at Bladder Neck								
	with Bone Anchors			w Bone Anchors - Suprapubic			without Bone Anchors		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death									
Transfusion							2/92	53%	(40 - 66)%
General Medical Complications									
Cardiovascular									
Febrile							1/47	2%	(0 - 10)%
Infection				1/49	0%	(0 - 5)%	1/20	25%	(10 - 46)%
Infection/Local Extension									
Neurologic									
Pulmonary									
Systemic - Abscess									
UTI							3/112	9%	(4 - 17)%
Operative Complications									
Bladder Injury							1/24	1%	(0 - 10)%
Bleeding									
Bleeding - Acute							3/112	11%	(3 - 24)%
Bleeding - Hematoma									
Bowel Injury									
Erosion Extrusion							2/143	12%	(2 - 36)%
Erosion Extrusion - Unknown				1/49	2%	(0 - 9)%	1/20	1%	(0 - 12)%
Erosion Extrusion - Urethral-Bladder				1/49	0%	(0 - 5)%	4/223	9%	(5 - 19)%
Erosion Extrusion - Vaginal		*							
Nerve Injury									
Operative CX - Other									
Osteomyelitis									
Ureteral Injury							1/98	1%	(0 - 12)%
Urethral Injury									
Urinary Tract Injury NS									
Vaginal Operative CX							1/98	20%	(14 - 30)%
Wound							1/98	40%	(31 - 50)%
Abdominal							1/98	26%	(18 - 35)%
Vaginal							1/20	1%	(0 - 12)%
Subjective Complications									
Pain				1/49	4%	(1 - 12)%	1/62	2%	(0 - 7)%
Sexual Dysfunction				1/49	4%	(1 - 12)%			
Voiding Dysfunction				1/49	0%	(0 - 5)%	2/122	16%	(3 - 38)%
Conversion									
Other Complications									

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel
Complications
ANY Prolapse**

	Slings								
	Xenograft								
	Synthetic at Midurethra			without Bone Anchors			Other Sling		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death									
Transfusion	9/3189	1%	(0 - 1)%				1/126	0%	(0 - 2)%
General Medical Complications									
Cardiovascular	2/2113	0%	(0 - 1)%						
Febrile	3/468	8%	(4 - 14)%						
Infection	1/1455	1%	(0 - 1)%	1/18	17%	(5 - 38)%			
Infection/Local Extension		*							
Neurologic	1/75	2%	(0 - 6)%						
Pulmonary									
Systemic - Abscess	2/111	3%	(1 - 9)%	1/10	60%	(30 - 85)%			
UTI	16/3016	7%	(5 - 9)%				1/126	1%	(0 - 4)%
Operative Complications									
Bladder Injury	29/4248	6%	(5 - 8)%				1/126	3%	(1 - 6)%
Bleeding									
Bleeding - Acute	6/1921	2%	(1 - 3)%				1/126	0%	(0 - 2)%
Bleeding - Hematoma	15/3770	3%	(2 - 4)%						
Bowel Injury		*							
Erosion Extrusion									
Erosion Extrusion - Unknown	6/632	4%	(2 - 7)%						
Erosion Extrusion - Urethral-Bladder	5/308	3%	(1 - 8)%						
Erosion Extrusion - Vaginal	6/2185	2%	(1 - 5)%						
Nerve Injury	3/1891	1%	(0 - 2)%						
Operative CX - Other									
Osteomyelitis									
Ureteral Injury									
Urethral Injury	5/1801	2%	(1 - 3)%				1/126	0%	(0 - 2)%
Urinary Tract Injury NS									
Vaginal Operative CX	3/393	1%	(0 - 3)%	1/18	17%	(5 - 38)%	1/126	5%	(2 - 10)%
Wound	2/301	2%	(0 - 6)%						
Abdominal	3/1612	1%	(0 - 2)%						
Vaginal	1/45	1%	(0 - 5)%						
Subjective Complications									
Pain	4/1985	3%	(1 - 7)%						
Sexual Dysfunction									
Voiding Dysfunction	9/2407	16%	(6 - 33)%						
Conversion									
Other Complications	1/193	1%	(0 - 2)%						

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel

Complications ANY Prolapse**	Injectables					
	Collagen			Artificial Sphincter		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death						
Transfusion						
General Medical Complications						
Cardiovascular				1/206	1%	(0 - 3)%
Febrile						
Infection						
Infection/Local Extension						
Neurologic						
Pulmonary						
Systemic - Abscess						
UTI	1/105	2%	(0 - 6)%			
Operative Complications						
Bladder Injury				2/206	15%	(10 - 22)%
Bleeding						
Bleeding - Acute						
Bleeding - Hematoma				1/179	4%	(2 - 8)%
Bowel Injury						
Erosion Extrusion						
Erosion Extrusion - Unknown				1/206	7%	(4 - 11)%
Erosion Extrusion - Urethral-Bladder				1/206	3%	(1 - 6)%
Erosion Extrusion - Vaginal						
Nerve Injury						
Operative CX - Other						
Osteomyelitis						
Ureteral Injury						
Urethral Injury				2/206	2%	(0 - 9)%
Urinary Tract Injury NS						
Vaginal Operative CX				2/206	13%	(6 - 22)%
Wound						
Abdominal				1/179	7%	(4 - 12)%
Vaginal						
Subjective Complications						
Pain						
Sexual Dysfunction						
Voiding Dysfunction						
Conversion						
Other Complications				1/206	3%	(2 - 7)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A16 -Complications rates - No Prolapse

SUI Guideline Update Panel

Complications — **Suspensions**

NO Prolapse

	All Retropubic Suspensions			Burch Suspension			Laparoscopic Suspension		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death	2/170	3%	(0 - 14)%	2/170	3%	(0 - 14)%			
Transfusion	6/321	6%	(2 - 12)%	4/169	9%§	(3 - 19)%	1/24	5%	(0 - 18)%
General Medical Complications									
Cardiovascular	6/592	2%	(1 - 4)%	3/294	3%	(1 - 8)%			
Dermatologic									
Febrile	7/426	8%	(5 - 12)%	3/113	11%	(5 - 20)%	1/60	0%	(0 - 4)%
Infection	1/98	2%	(0 - 6)%	1/98	2%	(0 - 6)%	1/31	4%	(0 - 14)%
Infection/Local Extension		*			*				
Neurologic	1/113	1%	(0 - 4)%	1/113	1%	(0 - 4)%			
Pulmonary	1/15	8%	(1 - 27)%				1/51	2%	(0 - 9)%
Systemic - Abscess	1/62	7%	(2 - 15)%	1/62	7%	(2 - 15)%			
UTI	17/1442	13%	(9 - 19%)	10/978	15%	(8 - 24)%	1/51	2%	(0 - 9)%
Operative Complications									
Bladder Injury	10/887	4%	(2 - 7)%	7/589	6%	(2 - 12)%	5/165	5%	(2 - 10)%
Bleeding									
Bleeding - Acute	3/433	4%	(1 - 9)%	2/334	2%	(0 - 6)%			
Bleeding - Hematoma	6/484	3%	(2 - 6)%	5/469	3%	(1 - 5)%	1/51	2%	(0 - 9)%
Bowel Injury	1/31	4%	(0 - 14)%	1/31	4%	(0 - 14)%	1/31	4%	(0 - 14)%
Erosion Extrusion - Unknown									
Erosion Extrusion - Urethral-Bladder	2/102	19%§	(1 - 70)%		*				
Erosion Extrusion - Vaginal									
Nerve Injury									
Osteomyelitis		*							
Ureteral Injury	5/1739	1%	(1 - 2)%	4/1640	1%	(1 - 2)%	3/57	11%	(1 - 42)%
Urethral Injury							2/55	2%	(0 - 10)%
Urinary Tract Injury NS	1/60	2%	(0 - 8)%						
Vaginal Operative CX									
Wound	13/1229	6%	(4 - 7)%	8/793	6%	(4 - 9)%	1/51	2%	(0 - 9)%
Wound - Abdominal	9/761	4%	(3 - 6)%	5/449	4%	(2 - 7)%			
Wound - Vaginal									
Subjective Complications									
Pain	9/980	5%	(3 - 8)%	6/756	6%	(3 - 12)%		*	
Sexual Dysfunction	8/989	4%	(2 - 6)%	5/801	3%	(2 - 4)%			
Voiding Dysfunction	6/636	9%	(5 - 15)%	5/583	10%	(5 - 18)%	1/60	5%	(1 - 13)%
Conversion	1/17	7%	(1 - 24)%	1/17	7%	(1 - 24)%	3/184	5%	(2 - 9)%
Other Complications	3/253	5%	(0 - 20)%	2/154	14%	(0 - 66)%	1/51	2%	(0 - 9)%

Note: G/P: G = Number of Groups/Treatment arms extracted /P = Number of Patients in those groups

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

Appendix A16 -Complications rates - No Prolapse

SUI Guideline Update Panel
Complications
NO Prolapse

	Slings								
	Autologous fascia			Autologous Vaginal Wall Slings			Cadaveric		
	without Bone Anchors			with/without Bone anchors			without Bone Anchors		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death	1/90	0%	(0 - 3)%						
Transfusion	3/194	4%	(1 - 11)%				1/63	0%	(0 - 4)%
General Medical Complications									
Cardiovascular	2/338	2%	(0 - 5)%						
Dermatologic									
Febrile									
Infection	1/71	0%	(0 - 3)%				1/63	7%	(2 - 14)%
Infection/Local Extension									
Neurologic	1/30	4%§	(0 - 15)%						
Pulmonary	1/91	1%	(0 - 5)%						
Systemic - Abscess							1/104	2%	(0 - 6)%
UTI	5/241	16%	(6 - 31)%	2/402	4%	(2 - 7)%	1/63	7%	(2 - 14)%
Operative Complications									
Bladder Injury	6/423	4%	(2 - 9)%	1/29	1%	(0 - 8)%			
Bleeding									
Bleeding - Acute	1/20	6%	(1 - 21)%						
Bleeding - Hematoma	1/247	1%	(0 - 3)%				1/104	1%	(0 - 4)%
Bowel Injury									
Erosion Extrusion - Unknown	1/33	1%	(0 - 7)%					*	
Erosion Extrusion - Urethral-Bladder	4/370	2%	(0 - 7)%				1/63	0%	(0 - 4)%
Erosion Extrusion - Vaginal				1/373	2%	(1 - 4%)		*	
Nerve Injury							1/104	1%	(0 - 4)%
Osteomyelitis									
Ureteral Injury									
Urethral Injury									
Urinary Tract Injury NS									
Vaginal Operative CX									
Wound	2/111	8%	(3 - 16)%						
Wound - Abdominal	1/247	1%	(0 - 3)%	2/402	5%	(3 - 8)%			
Wound - Vaginal									
Subjective Complications									
Pain	3/63	10%	(1 - 35)%						
Sexual Dysfunction	4/105	8%	(3 - 16)%						
Voiding Dysfunction		*					1/8	38%§	(12 - 71)%
Conversion									
Other Complications									

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Appendix A16 -Complications rates - No Prolapse

SUI Guideline Update Panel
Complications
NO Prolapse

	Slings: Synthetic at Bladder Neck								
	with Bone Anchors			w Bone Anchors - Suprapubic			w Bone Anchors - Transvaginal		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death									
Transfusion									
General Medical Complications									
Cardiovascular									
Dermatologic									
Febrile									
Infection									
Infection/Local Extension									
Neurologic									
Pulmonary									
Systemic - Abscess									
UTI									
Operative Complications									
Bladder Injury	1/11	10%§	(1 - 35)%						
Bleeding									
Bleeding - Acute									
Bleeding - Hematoma									
Bowel Injury									
Erosion Extrusion - Unknown									
Erosion Extrusion - Urethral-Bladder								*	
Erosion Extrusion - Vaginal	1/10	21%§	(4 - 50)%					*	
Nerve Injury									
Osteomyelitis		*		1/108	3%	(1 - 7)%			
Ureteral Injury									
Urethral Injury									
Urinary Tract Injury NS									
Vaginal Operative CX									
Wound									
Wound - Abdominal									
Wound - Vaginal									
Subjective Complications									
Pain									
Sexual Dysfunction									
Voiding Dysfunction									
Conversion									
Other Complications									

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
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Appendix A16 -Complications rates - No Prolapse

SUI Guideline Update Panel
Complications
NO Prolapse

	Slings								
	Synthetic at Bladder Neck								
	without Bone Anchors			Synthetic at Midurethra			Other Sling		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death				1/25	1%	(0 - 9)%			
Transfusion	1/200	1%	(0 - 3)%	3/569	2%	(1 - 4)%			
General Medical Complications									
Cardiovascular				2/261	1%	(0 - 3)%			
Dermatologic									
Febrile								*	
Infection									
Infection/Local Extension				2/174	7%	(4 - 13)%			
Neurologic									
Pulmonary									
Systemic - Abscess	2/315	3%	(1 - 5)%	1/25	1%	(0 - 9)%			
UTI	2/224	10%	(2 - 27)%	9/771	8%	(5 - 13)%			
Operative Complications									
Bladder Injury	1/200	1%	(0 - 2)%	23/1925	6%	(4 - 8)%			
Bleeding									
Bleeding - Acute				6/705	3%	(1 - 5)%			
Bleeding - Hematoma				7/1035	3%	(2 - 4)%			
Bowel Injury				3/256	1%	(0 - 4)%			
Erosion Extrusion - Unknown	2/501	17%§	(9 - 28)%	6/621	1%	(0 - 3)%			
Erosion Extrusion - Urethral-Bladder	3/346	3%	(1 - 9)%						
Erosion Extrusion - Vaginal	6/591	8%	(4 - 15)%	9/891	7%	(2 - 15)%		*	
Nerve Injury	1/200	1%	(0 - 2)%	1/404	0%	(0 - 1)%			
Osteomyelitis									
Ureteral Injury									
Urethral Injury					*			*	
Urinary Tract Injury NS									
Vaginal Operative CX				2/302	2%	(0 - 7)%			
Wound	2/385	7%	(3 - 14)%	3/280	2%	(1 - 5)%			
Wound - Abdominal				2/75	2%	(0 - 8)%			
Wound - Vaginal				4/189	4%	(1 - 7)%			
Subjective Complications									
Pain	2/264	9%	(2 - 23)%	2/512	1%	(0 - 3)%			
Sexual Dysfunction				1/62	0%	(0 - 4)%			
Voiding Dysfunction				1/1175	2%	(1 - 3)%			
Conversion								*	
Other Complications									

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Appendix A16 -Complications rates - No Prolapse

SUI Guideline Update Panel

Complications

NO Prolapse

	Injectables								
	Collagen			Other Non-degradable synthetics			Artificial Sphincter		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death							1/25	5%	(0 - 17)%
Transfusion									
General Medical Complications									
Cardiovascular									
Dermatologic	3/399	5%	(1 - 17)%						
Febrile									
Infection									
Infection/Local Extension									
Neurologic									
Pulmonary	1/60	2%	(0 - 8)%						
Systemic - Abscess	1/115	1%	(0 - 4)%						
UTI	6/381	10%	(5 - 17)%						
Operative Complications									
Bladder Injury									
Bleeding									
Bleeding - Acute	4/251	5%	(3 - 8)%						
Bleeding - Hematoma									
Bowel Injury									
Erosion Extrusion - Unknown							1/18	28%§	(11 - 51)%
Erosion Extrusion - Urethral-Bladder									
Erosion Extrusion - Vaginal									
Nerve Injury									
Osteomyelitis									
Ureteral Injury									
Urethral Injury		*			*				
Urinary Tract Injury NS									
Vaginal Operative CX									
Wound									
Wound - Abdominal									
Wound - Vaginal									
Subjective Complications									
Pain		*							
Sexual Dysfunction									
Voiding Dysfunction									
Conversion									
Other Complications	3/342	27%§	(2 - 76)%				1/18	23%§	(8 - 45)%

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